
7 Technical Specifications

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All specifications are subject to change without notice.

Operating Modes - AEM Monitoring

POST Mode

The **POWER ON SELF TEST** function (POST) activates each time you turn on the AEM Monitor after the monitor has been OFF for 30 seconds. In POST, each of the indicators illuminates for six seconds and two tones sound.

Monopolar Operating Mode

The AEM Monitor detects improper setup conditions and detects operative faults by providing a monitored pathway for the current which is flowing from the shield to the patient return electrode. Fault conditions are indicated on the front panel and the electrosurgical generator is signaled to disable its output. Operative faults also generate an audible alarm.

Bipolar Operating Mode

The AEM Monitor measures the RF current flowing between the elements of a bipolar accessory. A number of segments on the display illuminate corresponding to the magnitude of current flowing between the tines of the accessory. The indicated current range is 0.1 A to 1.1 A. The AEM Monitor clicks at a rate proportional to the indicated current and the click volume is adjustable to high, low, and off. A remote visual display may be plugged into the monitor and placed in a convenient viewing position.

Functional Characteristics

Monopolar Setup Fault Detection

If the shield or return electrode are disconnected, causing a setup fault, a yellow indicator illuminates to identify the deficiency and the AEM Monitor opens one side of the return electrode circuit causing the electrosurgical generator to detect a pad fault and disable its output.

Shield Cable and Return Electrode Switch Threshold

50 ohms \pm 20%

Monopolar Operative Fault Detection

If there is excessive shield current or arcing between the shield and the active electrode causing an operative fault, a red indicator illuminates to identify an insulation fault, an audible alarm is generated, and the AEM Monitor opens one side of the return electrode circuit causing the electrosurgical generator to detect a pad fault and disable its output.

Radio Frequency Current Sensing

Current-sensing and spark detection are provided.
Minimum electrosurgical generator output for reliable insulation fault detection: 20 Watts

Bipolar Current Measurement

The number of segments illuminated in the bar-graph display correspond to the magnitude of the bipolar current. In addition to the visual display, the AEM Monitor generates clicks at a rate proportional to the measured current and the click volume is adjustable to high, low, or off.

Accuracy: 10% of full scale
Range: 0.1 to 1.1 Ampere
Maximum current without damage: 3.0 Amperes
Click Rate: 25 to 40 Hz at 1.0 Ampere

Remote Bipolar Current Indication

An End Point Monitor Remote Display (EMR) is available which can be placed in a convenient viewing position. The Encision End Point Monitor Remote Display (EMR) indicates the same information as the front panel display, but when the Encision End Point Monitor Remote Display (EMR) is plugged into the **REMOTE DISPLAY** connector, the front panel display is inactive.

Cord Length: 15 feet (4.6 meters)

Duty Cycle

Continuous

Indicators and Alert Functions

Setup Fault Indicators

AEM CORD, yellow light

Indicates that the AEM Cord, AEM cord adapter, or the instrument is not properly connected to the AEM Monitor.

RETURN ELECTRODE, yellow light

Indicates that the return electrode is not properly connected, the adapter is malfunctioning, or that a dual pad electrode is not being used.

Operative Fault Indicators

INSULATION, red light

Indicates that there is excessive current or arcing between the active electrode and the shield. Once triggered, the insulation light stays on for 30 seconds. Immediately upon detection of fault, one beep; after approximately 4 seconds, 3 beeps. The audio volume is fixed and cannot be turned off.

Status Indicators

POWER, green light

Indicates that the AEM Monitor is plugged in and turned on.

READY, green light

Indicates that there are no faults and that the electrosurgical generator can be activated. Stays off for ten seconds after operative fault.

Bipolar Current Indicators

RF AMPERES

30 segment bar-graph display

The number of segments illuminated in the bar-graph display correspond to the magnitude of the bipolar current as indicated on the scale underneath.

Audible Indication, adjustable volume clicks. The clicks are delivered at rate proportional to indicated current.

Connectors and Cables

AEM CORD

Connects the AEM Instrument active conductor to the electrosurgical generator and shield conductors to the AEM Monitor, both via the AEM Cord Adapter.

Length: 121"

Inhibit Adapter, green block attached by means of a cable to front panel

Cable length: 15" (38 cm)

Dual area, Return Electrode plug on one face which connects to the electrosurgical generator.

Dual area, Return Electrode receptacle on opposite face which connects to Return Electrode plug attached to the actual return electrode. Senses the pin of a dual area return electrode.

AEM CORD receptacle on front panel

A unique, two-conductor receptacle which receives the AEM Cord Adapter. There is no preferred polarity.

BIPOLAR GENERATOR jacks, two arranged vertically on front panel

Two standard banana jacks.

Provided for connecting to the bipolar electrosurgical generator.

There is no preferred polarity.

Bipolar Jumper Cord, dual banana plugs on each end of a cord

Provided for connecting the AEM Monitor to the bipolar electrosurgical generator. Retention Bracket provided. (For EM2+E only)

There is no preferred polarity.

BIPOLAR ACCESSORY jacks, two arranged horizontally on front panel

Two standard banana jacks.

Provided for connecting to the bipolar accessory.

There is no preferred polarity.

REMOTE DISPLAY jack, mounted on rear panel

Four pin, male, XLR series, panel receptacle.

Provided for connecting to the remote display cable. Attaching the cable activates the remote display and deactivates the front panel display of bipolar current.

Power Receptacle, mounted on rear panel

UL/IEC type receptacle containing two, 0.5 Amp., 250V, fast blow, 5 x 20 mm fuses (one for each side of the line).

Power Cord, attached to power receptacle

A 15' long, 16/3 power cord with a three-prong, hospital-grade plug.

A 10' long, VDE approved power cord (220-240V AC)

Electrical Characteristics

Input Power Requirements 115 Volt

115 V~ nominal
105 - 130 Volts 47 - 63 Hz
Normal current drain 0.2 A
Maximum current 0.5 A

Input Power Requirements 220-240 Volt

230 V~ nominal
220 - 240 Volts ~, 47 - 63 Hz
Normal current drain 0.2 A
Maximum current 0.5 A

Chassis Source Leakage Current

100 μ A maximum

Patient Leakage Current

Source or sink leakage current is 10 μ A maximum

Dimensions and Weight

External Dimensions

13.0 in. (33.0 cm) wide x 20 in. (50.8 cm) long x 2.5 in. (6.35 cm) high
(does not include feet). Feet raises chassis 0.5 in. (1.3 cm).

Weight

8.0 lbs (3.63kg)

Environmental Characteristics

Operating Temperature

50 to 122° F (10 to 50° C)

Storage and Transport Temperature

-13 to 158° F (-25 to 70° C)

Operating, Storage and Transport Humidity

5% to 95% relative, noncondensing

Atmospheric Pressure (Operating, Storage and Transport)

50 - 110 kPa

Standards and IEC Classifications

Class I Equipment per IEC 60601-1/EN 60601-1

Protection against electrical shock is provided by connection of accessible conductive parts to the protective ground conductor in such a way that they cannot become live in the event of a failure of basic insulation.

Type CF Equipment per IEC 60601-1/EN 60601-1

The Active Electrode Monitor provides a high degree of protection against electrical shock, particularly regarding allowable leakage currents and has a CF type isolated (floating) applied part.

Manufacturer's declaration – electromagnetic emissions (EN 60601-1-2:2002 Table 201)		
The Encision AEM Monitor and accessories are intended for use in the electromagnetic environment specified below. The customer or user of the equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AEM Monitor and accessories uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The AEM Monitor and accessories is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration – electromagnetic immunity (EN 60601-1-2:2002 Table 202)			
The Encision AEM Monitor and accessories are intended for use in the electromagnetic environment specified below. The customer or user of the equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T = 230VAC 50Hz and 110VAC 50Hz	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T = 230VAC 50Hz and 110VAC 50Hz	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AEM Monitor and accessories requires continued operation during power mains interruption, it is recommended that the AEM Monitor and accessories be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	50 and 60 Hz, 3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity (EN 60601-1-2:2002 Table 204)			
The Encision AEM Monitor and accessories are intended for use in the electromagnetic environment specified below. The customer or user of the equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms 150kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the AEM Monitor and accessories, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur on the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AEM Monitor and accessories is used exceeds the applicable RF compliance level above, the equipment should be observed to verify to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the AEM Monitor and accessories (EN 60601-1-2:2002 Table 206)			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

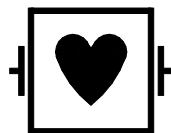
Notice

ORDINARY EQUIPMENT IS NOT PROTECTED AGAINST THE INGRESS OF WATER.

SUITABLE FOR USE WITH EITHER FLOATING OR GROUND REFERENCED ELECTROSURGICAL GENERATORS AT CONTROL SETTINGS PRODUCING 3750 V PEAK TO PEAK OR LESS.



ATTENTION: Consult accompanying documents



Type CF Equipment with defibrillator protection



Ground

Compatible Products

For successful operation, the AEM Monitor must be used with a set of compatible products. This includes; an electrosurgical generator with contact quality monitor, a return electrode, an active electrode, active cable, and trocar cannula.

Note: Generators must have contact quality monitoring implemented for return electrode

Electrosurgical Generator 115 V models	EM2 Discontinued	EM2+	EM2HF	EM2B Discontinued	EM2M Discontinued
Bard 5000* (with pad sensing) ¹	-	X	-	-	-
Birtcher 4400 – Power Plus ¹ <i>Excision catalog number ES9008 needed for compatibility with EM2HF</i>	-	-	X	X	-
Bovie IDS-300 <i>Excision catalog number ES9008 needed for compatibility with EM2+</i>	-	X	-	-	X
ConMed / Aspen Labs Excalibur Sabre 2400 ¹ System 5000/2500 * <i>* Excision catalog number ES9007 and ES9005A needed for compatibility.</i>	X X -	X X X	- - -	- - -	- - -
Erbe (with mounting pad between ESU and Monitor) ICC 200 ¹ ICC 300 *** ICC 350 ¹ <i>Excision catalog number ES9008 needed for compatibility with EM2+ *** Limit the ESU in all modes to a power setting of 50 watts maximum with 45cm instruments</i>	- - -	X X X	- - -	- - -	X X X
Medtrax O.R. Pro 300 ¹ <i>Excision catalog number ES9008 needed for compatibility with EM2+</i>	-	X	-	-	X
Megadyne MegaPower	-	X	-	-	-
Olympus UES-40 (except "Saline" mode) <i>Excision catalog number ES9008 needed for compatibility with EM2+</i>	-	X	-	-	X
Valleylab Force 2 Force FX Force FXC Force EZ Force 40 Series ¹ SSE2L ¹ <i>*** Limit the ESU in Spray coag mode to a power setting of 45W maximum with 45cm electrodes</i>	X - - - X	X X X X	- - - -	- - - -	- - - -
<i>* Not tested with 45cm Instruments</i>					

Electrosurgical Generator 230V models	EM2+E
ConMed / Aspen Labs Excalibur Plus ConMed System 5000/2500 * <i>* Excision catalog number ES9007 and ES9005A needed for compatibility.</i>	X X
Valleylab Force 2 ¹ Force 40S ¹ Force FX-8 ¹	X X X
<i>¹ Not tested with 45cm Instruments</i>	

Return Electrodes

The AEM Monitoring System requires a dual-area return electrode. The following products are designed to be used with electrosurgical generators having contact quality monitoring systems.

Aspen, 3M, NDM, Valleylab, and others